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TITLE: METHODS FOR APPLYING A COVERING LAYER TO A STENT

APPLICANT: GORAN LUKIC

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Date of Deposit May 15, 1998

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1. Letter Transmitting Appeal Brief (1 page);
2. Appeal Brief (in triplicate) (11 pages); and
3. Postcard.

Liz DeMinico

(Typed or printed name of person mailing paper or fee)

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Express Mail No. EI746567763US

Docket No.: **PC8432B**

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of:)

GORAN LUKIC) Examiner: **S. Maki**

Serial No.: **08/636,206**)

Filed: **April 22, 1996**) Art Unit: **1733**

For: **METHODS FOR APPLYING A
COVERING LAYER TO A STENT
(AS AMENDED)**)

Assistant Commissioner of Patents
Washington, D.C. 20231

Sir:

LETTER TRANSMITTING APPEAL BRIEF

- An Appeal Brief is submitted herewith in triplicate. The Commissioner is hereby authorized to charge the requisite \$310.00 fee under 37 C.F.R. § 1.17(f) to Deposit Account No. 16-1445.
- The Commissioner is hereby authorized to charge any additional fees which may be required under 37 C.F.R. 1.16 and 1.17, or credit any overpayment, to Deposit Account No. 16-1445.

Respectfully submitted,

Date: May 15, 1998

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IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

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APPEAL BRIEF

I) **Real Party In Interest**

Assignee Schneider (Europe) GmbH.

II) Related Appeals and Interferences

None.

III) Status of Claims

Claims 1-14, 18-19, and 23-29: canceled.

Claims 15-17 and 20-22: pending, appealed

IV) Status of Amendments

Claim 25 was canceled by way of an Amendment After Final Rejection. Claims 23-24 and 26-29 were canceled by way of a Second Amendment After Final Rejection. 35206

v) Summary of Invention

The present invention relates to methods of applying a polymeric cover to a stent. A polymeric tube is pre-formed (3:19-23). With reference to Figure 1, a stent 1 is disposed in the pre-formed cover 3 and then radially expanded or allowed to expand in the cover 3 (4:9-12). The cover

3 is attached to the stent 1 by chemical bonding (5:11-21), curing an adhesive medium (5:29-31), or polymerizing an elastomeric composition (5:32-6:4).

An advantage of the claimed process is its simplicity. The resulting covered stent, which is illustrated in Figure 2, may have the cover intimately bound to the stent to reduce the possibility of separation when implanted (2:23-26).

VI) Issues

- (i) Are claims 15-17 and 20-22 adequately described in accordance with 35 U.S.C. § 112, first paragraph?
- (ii) Are claims 15-17 and 20-22 patentably distinguishable, in view of 35 U.S.C. § 103(a), from MacGregor (U.S. Patent No. 5,015,253) in view of Gianturco (U.S. Patent No. 5,282,824), Kaster (U.S. No. 4,444,215), and the “official notice” of three separate facts, and optionally further in view of Simon et al. (U.S. Patent No. 5,384,308)?

VII) Grouping of Claims

Appellant presents the claims as a single group appended hereto as Section IX.

VIII) Arguments

(A) Summary

The obviousness rejection relies upon a combination of three documents, official notice of three separate facts, and optionally a fourth document, to reject Appellant’s simple process for making a covered stent. The primary document teaches a bare (uncovered) stent which requires an “open architecture” to integrate into a blood vessel, thus teaching away from the present method of covering a stent. There is no teaching or suggestion to combine the secondary documents. The rejections also rely upon impermissible picking and choosing.

(B) Statutory Authorities

35 U.S.C. § 112: The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same, and shall set forth the best mode contemplated by the inventor of carrying out his invention.

35 U.S.C. § 103(a): A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negative by the manner in which the invention was made.

(C) Analysis

1. Rejection of claims 15-17 and 20-29 under 35 U.S.C. § 112, first paragraph

Each of the claims on appeal contain a process step of radially expanding a stent or allowing a stent to expand within a tube. The Examiner contends that this application fails to support “expanding” a stent within a tube versus allowing the stent to expand (see Advisory Action, paper no. 11, 2:15 - 3:18). However, literal support for “expanding” is found in the specification at several locations:

“This invention relates to a stent with a discontinuous *expandable* wall comprising on at least a portion of its length a continuous covering layer of elastic material with an outer surface surrounding the discontinuous wall.” (1:4-8, emphasis added.)

“Furthermore, the liaison of the covering layer with the discontinuous wall of the stent eliminates any delicate, time and skill consuming efforts and allows coating of any kind of discontinuous *expandable* stent wall. (2:31 - 3:1, emphasis added.)

“In addition, the invention is not limited to the embodiment shown, *being applicable to any kind of expandable stent* having a discontinuous wall.” (5:2-5, emphasis added.)

“As a variant of this method, the inside of the tube may be coated with an elastomeric polymerisable composition dissolved in an amount of solvent permitting contact forming, whereby *after expansion of the stent* the solvent is allowed to evaporate and the elastomeric coating adhered by contact to the tube and to the stent is polymerized.” (6:24-30, emphasis added.)

Thus, the specification literally discloses “expansion” of an “expandable stent” - in other words “expanding” a stent.

In any event, it is well settled that the specification need only be reasonable with respect to the art involved. Appellant “need not inform the layman nor disclose what the skilled already possess.

[Appellant] need not describe the conventional. . . . The intricacies need not be detailed ad absurdum.” *General Electric Co. v. Brenner*, 159 USPQ 335, 337 (D.C. Cir. 1968). In addition, “[a]dequate description under the first paragraph of 35 U.S.C. 112 does not require literal support for the claimed invention.... Rather, it is sufficient if the originally-filed disclosure would have conveyed to one having ordinary skill in the art that an Appellant had possession of the concept of what is claimed. *Ex parte Parks*, 30 USPQ 2d 1234, 1236B37 (B.P.A.I. 1993).

The invention is applicable to any kind of expandable stent (5:2-5). One skilled in the art would understand that balloon expandable stents known in the art are conventionally radially “expanded.” Accordingly, those skilled in the art possessed the knowledge that certain expandable stents are expanded (versus allowed to expand), and the application contains an adequate description.

In view of the foregoing, Appellant respectfully submits that the rejections under 35 U.S.C. § 112, first paragraph, are in error, and should be withdrawn.

2. Rejection of claims 15-17 and 20-29 under 35 U.S.C. §103(a) for alleged obviousness

Appellant’s invention relates to a method for covering a stent. Each claim includes steps relating to the pre-forming of a polymeric tube, placing a stent into the tube, then radially expanding the stent or allowing the stent to expand in the tube. The cover is attached to the stent by chemically bonding (claims 15, 20); curing adhesive medium (claims 16, 21); or polymerizing an elastomeric composition (claims 17, 22).

The invention is a simple process for making an implantable device. The obviousness rejection, which relies upon numerous documents and official notice, does not establish a *prima facie* case of obviousness for the following reasons:

(a) **There is no Suggestion to Combine the Cited Documents**

(i) Primary Reference MacGregor (U.S. Patent No. 5,015,253) teaches away from a process of making a covered stent

According to MacGregor:

Because of the *open architecture* of the external surface of the stent 21, the endothelial tissue of the blood vessel or other hollow organ is not destroyed during a dilation procedure. Furthermore, the patches of endothelium which may be present *in the pores of the stent 21* will facilitate the quick integration of the stent 21 into the wall of blood vessel or the like.

U.S. Patent No. 5,015,253, column 5, lines 44-50, emphasis added. Thus, MacGregor teaches that his stent has an open architecture which allows it to function by integrating into the wall of a blood vessel. It teaches away from a stent with a covering, as such a covering would destroy the integration function of the uncovered stent. One skilled in the art would not combine the uncovered stent of MacGregor with secondary documents relating to covered stents as such a combination would defeat the function of MacGregor's stent. In sum, this document teaches away from covering a stent, which is the essence of Appellant's invention.

(ii) Gianturco (U.S. Patent No. 5,282,824) does not suggest bonding a portion of a stent to a tube

Gianturco is quite explicit that its sleeve is only attached to the ends of a stent:

"The stents 11 and 12 are attached to sleeve 13, which in this case is nylon, by stitching or gluing *the joints 17 at either end of the stent assembly* to the sleeve 13. If the sleeve were made of plastic, the stents could be attached to the sleeve by embedding the stents in the plastic, it being understood that the means for attaching the stents to the sleeve can be varied depending on the sleeve materials, and other factors, without diverging from the intended scope of the present invention (2:56-65, emphasis added; see also 3:41-45).

Thus, Gianturco teaches away from a method which involves bonding a portion of a stent to a tube.

(iii) Kaster (U.S. Patent No. 4,441,215) does not suggest combination with an expandable stent

Kaster relates to a vascular graft having two layers. It does not suggest a combination of a stent and a covering. More importantly, it does not suggest radially expanding an inner layer or allowing an inner layer to expand as part of its manufacture. Thus, there is no teaching or suggestion to combine Kaster with the other cited documents.

(iv) Simon et al. (U.S. Patent No. 5,354,308) does not suggest bonding a pre-formed sleeve

Simon et al. purportedly discloses a stent having an elastomeric sleeve. However, Simon et al. does not teach or suggest bonding a pre-formed tube to a stent. Accordingly, it should not be combined with the other cited documents to reject Appellant's claims.

(v) There is no teaching to combine the items of official notice

The Examiner has taken official notice of three separate facts relating to adhesives, elastomeric compositions, and bonding methods that are allegedly well known/conventional in the bonding art. However, the Examiner "did not assert that these separate facts are known in combination." (Paper no. 11, 8:20-21). Thus, these facts provide no teaching or suggestion to combine the cited documents.

(b) The Rejections Rely Upon Impermissible "Picking and Choosing"

The Examiner's rejections rely upon a combination of isolated statements from the prior art which have been taken out of context.

(i) It is alleged that MacGregor, at column 1, line 65 to column 2, line 50, teaches the steps of compressing a stent and subsequently expanding a stent. However, MacGregor's teachings relate to compressing a stent to load it into a catheter for delivery and subsequently expanding the stent from the delivery device into a body vessel. These isolated statements relate to a method of *using* an *uncovered* stent, and not to a method of *making* a *covered* stent. In fact, MacGregor's uncovered stent, once expanded in the body vessel in its intended use,

is incapable of being covered by subsequent manufacturing steps (unless first surgically removed). MacGregor's disclosure is limited to an uncovered stent having an "open architecture" which becomes integrated in a body vessel, thus teaching away from the proposed combination to yield a covered stent.

(ii) The Examiner also relies on "bonding" recitations in MacGregor. But these recitations relate to the bonding of stent elements to each other, and do not relate to the bonding of a stent to a cover: "The present invention may include bonding points 34 *where one portion of the strand engages another portion thereof and at which the strand material is bonded to itself.* ... Bonding may be accomplished in a variety of ways. Thermal bonding may be achieved by drawing and laying down the *strand* . . . Adhesive, which may be biocompatible and hemocompatible, may also be used for bonding purposes." (Column 5, lines 8-37, emphasis added). Thus, these recitations should not be relied upon to reject the claims which relate to bonding a stent to a cover.

(iii) The Examiner also relies on recitations of "coating" in MacGregor. However, these recitations relate to coatings to provide biocompatibility for MacGregor's stent, and not to covering a stent with a pre-formed tube. (See, 5:51-56.) This recitation must be read together with MacGregor's teaching that the stent is uncovered to function (5:44-50).

Thus, the obviousness rejection relies upon isolated recitations concerning an uncovered stent which is loaded in a catheter and subsequently deployed (still uncovered) in a body lumen wherein the stent elements are bonded to one another (and not to a cover) and coated for biocompatibility and hemocompatibility (while maintaining an open architecture). These recitations are taken out of context and combined to arrive at Appellant's method of making a stent covered by a pre-formed tube.

The Examiner's combination violates the clear standard established by the Federal Circuit against hindsight reconstruction:

It is permissible to use the claimed invention as an instruction manual or 'template' to piece together the teachings of the prior art so that the claimed invention is rendered obvious. This court has previously stated that '[o]ne cannot use hindsight reconstruction to pick and choose among isolated disclosures in the prior art to deprecate the claimed invention.'

In re Fritch, 972 F.2d 1260, 23 USPQ 2d 1780 (Fed. Cir. 1992) (quoting In re Fine, 837 F.2d 1071, 1075, 5 USPQ 2d 1596, 1600 (Fed. Cir. 1988)).

Appellant respectfully submits that the rejections as presented rely heavily on impermissible hindsight. Accordingly, it is requested that the rejections under 35 U.S.C. § 103(a) be withdrawn.

(D) Conclusions

(i) Claims 15-17 and 20-22 comply with 35 U.S.C. § 112, first paragraph, as Appellant's specification contains literal support and an adequate description for radially "expanding" a catheter.

(ii) Appellant's inventions are patentable over the documents of record.

A *prima facie* case of obviousness has not been established for claims 15-17 and 20-22 because:

- (a) there is no suggestion to combine or modify the cited prior art documents; and
- (b) the rejections rely upon impermissible picking and choosing.

In view of the foregoing, Appellant respectfully requests favorable action in this Appeal and allowance of the claims. The consideration of this Appeal Brief by the Board of Patent Appeals and Interferences is appreciated.

Respectfully submitted,

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IX) Appendix

15. A method for applying a covering layer to a stent comprising:

- (a) forming a tube made out of an elastomeric polymerisable composition;
- (b) radially contracting the stent;
- (c) inserting into the tube at least a portion of the stent; and
- (d) radially expanding at least the portion of the stent in the tube or

allowing at least the portion of the stent to expand in the tube, and chemically bonding at least the portion of the stent and the tube together.

16. A method for applying a covering layer to a stent comprising:

- (a) forming a tube made out of an elastomeric polymerisable composition, the tube having an inside;
- (b) coating the inside of the tube with an adhesive medium;
- (c) providing a stent having at least one portion along its length, and radially contracting the stent;
- (d) inserting into the tube at least one portion of the stent;
- (e) radially expanding the at least one portion of the stent in the tube or allowing the at least one portion of the stent to expand in the tube; and
- (f) curing the adhesive medium between the inside of the tube and the at least one portion of the stent in the tube.

17. A method for applying a covering layer to a stent comprising:

- (a) forming a tube from an elastomeric polymerisable composition, the tube having an inside;
- (b) preparing an elastomeric composition dissolved in a solvent;
- (c) coating the inside of the tube with the elastomeric composition dissolved in the solvent;

- (d) providing a stent having at least one portion along its length, and radially contracting the stent;
- (e) inserting into the tube at least one portion of the stent;
- (f) radially expanding the at least one portion of the stent in the tube or allowing the at least one portion of the stent to radially expand in the tube;
- (g) evaporating the solvent; and
- (h) polymerizing the elastomeric composition between the inside of the tube and the at least one portion of the stent in the tube.

20. A method for covering a stent comprising:

- (a) forming a polymeric tube having an inner surface;
- (b) inserting a contracted stent into the tube, the stent having an inner surface and an outer surface;
- (c) radially expanding the stent or allowing the stent to radially expand in the tube so that at least part of the stent outer surface makes contact with at least part of the tube inner surface; and
- (d) chemically bonding at least a part of the outer surface of the stent to the inner surface of the tube.

21. A method for covering a stent comprising:

- (a) forming a polymeric tube having an inner surface;
- (b) coating the inner surface of the tube with an adhesive medium;
- (c) inserting a contracted stent into the tube;
- (d) radially expanding the stent in the tube or allowing the stent to radially expand in the tube; and
- (e) curing the adhesive medium or allowing the adhesive medium to cure.

22. A method for covering a stent comprising:

- (a) forming a polymeric tube, the tube having an inner surface;
- (b) coating at least a part of the inside of the tube with a polymerisable composition;
- (c) inserting a contracted stent into the tube, the stent having an inner surface and an outer surface;
- (d) radially expanding the stent in the tube or allowing the stent to radially expand in the tube; and
- (e) polymerizing the polymerisable composition.